IFW AF/3738

Attorney's Docket No.:«Matter Matter ID»

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Saumil N. Merchant et al.	Art Unit	: 3738
Serial No.	: 09/625,644	Examiner	: D. Isabella
Filed	: July 26, 2000		
Title	: MIDDLE-EAR IMPLANT		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF NON-COMPLIANCE

In response to the Notice of Non-Compliance mailed on May 20, 2004, Applicant submits, in triplicate, an appeal brief that incorporates the content of the appeal brief filed on March 19, 2004, together with the appendix of claims as filed on May 19, 2003.

No fees are believed to be due. However, to the extent fees are dues, or if a refund is forthcoming, please adjust our Deposit Account No. 06-1050, referencing Attorney Docket No. 00633-025001.

Respectfully submitted,

Date: June 16, 2004

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CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

June 16, 2004
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Signature

Irja Zarembok
Typed or Printed Name of Person Signing Certificate

Attorney's Docket No.: 00633-025001

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Mail Stop Appeal Brief - Patents
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BRIEF ON APPEAL

Applicant appeals the final rejection of claims 1-26 in the final action dated November 18, 2002. A notice of appeal was filed on February 19, 2003.

Applicant requests that the rejection of claims 1-26 be reversed.

(1) REAL PARTY IN INTEREST

The real party in interest is the Massachusetts Eye and Ear Infirmary, a Massachusetts corporation having a place of business at 243 Charles Street, Boston, Massachusetts, as evidenced by an assignment executed July 24, 2000 and submitted for recordation at the U.S. Patent Office on July 26, 2000. The assignment was recorded at reel 01097 frame 0540 on July 26, 2000.

(2) RELATED APPEALS AND INTERFERENCES

Neither Applicant, nor Applicant's legal representative, nor the assignee are aware of any appeals or interferences that will directly affect or be affected by or have a bearing on the Board's decision in the pending appeal.

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March 19, 2003
Date of Deposit

Signature

Irja Zarembok
Typed or Printed Name of Person Signing Certificate

(8) ARGUMENT

Double Patenting Rejection

Claims 1-26 stand rejected for obviousness-type double-patenting over U.S. Patent 6,251,138, which is the parent of the pending application. In a response to the office action of May 30, 2002, in which the Examiner issued the present double-patenting rejection, Applicant submitted a terminal disclaimer.

In view of the terminal disclaimer, Applicant requests withdrawal of this double-patenting rejection.

Section 112 rejection of claim 2

Claim 2 stands rejected as allegedly being indefinite for failure to particularly point out the subject matter of the invention. In particular, the Examiner states that there is no support for "its [physical] volume."

In response to the final office action, Applicant proposed a formal amendment that would have addressed this issue. However, the Examiner declined to enter this amendment because it allegedly did not place the application in better condition for appeal.

Even in the absence of this amendment, Applicant submits that claim 2 satisfies 35 USC 112. The standard for determining whether a claim is indefinite is

> "whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification."[4]

The exact term "physical volume" is not used in the specification. However, Applicant does use the term "actual volume" to distinguish the volume of the balloon, as one would physically measure it, from the equivalent volume, which is measured in terms of the balloon's ability to transmit sound.[5] Hence, the notion of two different types of "volume" is clearly set forth in the specification.

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[4] *North American Vaccine, Inc. v. American Cyanimid*, 7 F. 3d 1571 (CAFC 1993), cert. denied 511 U.S. 1069 (1993)

[5] See specification at page 7, lines 19-21 ("Throughout this specification, the equivalent volume is expressed in terms of a percentage of the balloon's actual volume.")

Applicant submits that one of ordinary skill, after having read the specification, would recognize the existence of two kinds of "volume," namely "equivalent volume" and "actual volume." That person would then recognize that "physical volume" in claim 2 must correspond to the "actual volume," since no other type of volume is discussed in the specification. This recognition is reinforced by the adjective "physical," which suggests the volume obtained from a physical measurement, i.e. an "actual" volume.

Since one of ordinary skill would have no difficulty ascertaining the scope of claim 2, Applicant requests that the rejection of claim 2 under 35 USC 112 be reversed.

Section 103 rejection of claim 2

The Examiner asserts that claim 2 is rendered obvious by *Nadol*.

The final office action suggests that there is some confusion concerning "what value defines an acoustic impedance corresponding to the equivalent volume." An explanation can be found in the specification beginning on the last paragraph of page 7. This explanation is summarized as follows:

A 21 microliter air bubble will have some acoustic impedance. Similarly, a 30 microliter balloon will also have an acoustic impedance. If these two acoustic impedances are the same, then, since 21 microliters is 70% of 30 microliters, we say that the balloon has an acoustic impedance equivalent to 70% of its physical volume. Such a balloon would be within the scope of the claim. A 30 microliter balloon whose equivalent impedance is that of a 1 microliter air bubble, for example, would lie outside the scope of the claim.

According to the Examiner, *Nadol* renders claim 2 obvious The Examiner does not, however, indicate where *Nadol* teaches or suggests the balloon recited in claim 2. After careful scrutiny of *Nadol*, Applicant has been unable to identify any teaching or suggestion of "a balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of its physical volume." In fact, Applicant has been unable to find any mention of "equivalent volume" whatsoever in *Nadol*.

To establish a prima facie case of obviousness, the Examiner must, among other things, set forth the differences between the prior art and the claims at issue.[6] In the case of claim 1, the Examiner has failed to do this. All the Examiner has done is make the conclusory assertion:

"[i]t appears that Nadol (138) has an equivalent volume of at least 70%."

Such an assertion, completely devoid of support from the cited reference, does not rise to the level of a prima facie case of obviousness. Accordingly, Applicant requests that the section 103 rejection of claim 2 be reversed.

Section 102(b) rejection based on Nadol

Claims 1 and 22 stand rejected as being anticipated by *Nadol*.[7] In support of this rejection, the Examiner draws attention to a passage in *Nadol* that states:

> "[i]n a preferred embodiment, the bubble is formed of a thin pliant material effective to achieve a good impedance match between the tympanum and the round window"[8]

Although this passage does not refer expressly to "equivalent volume," there is a relationship between equivalent volume and acoustic impedance. As best understood, the Examiner concludes from this that a balloon that is impedance matched to the tympanum and round window *necessarily* has an equivalent volume consistent with the limitation recited in claim 1. From this, the Examiner concludes that *Nadol* discloses the claimed balloon.

The Examiner appears to assume that by simply implanting a balloon whose impedance matches that of the tympanum and round window, one can restore hearing in a patient having a fluid-filled middle ear.

In making this assumption, the Examiner is merely repeating the same conceptual mistake that Applicant himself made at one time. Had the Examiner subjected his assumption to experimentation, he may have realized, as has the Applicant, that the assumption is incorrect. Indeed, the Examiner's reluctance to concede possible error in this assumption is a testament

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[6] *Graham v. John Deere*, 383 U.S. 1 (1966) ("Under sec. 103, the scope and content of the prior art are to be determined, difference between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.").

[7] *Nadol, Jr.*, U.S. Patent 5,480,433 and U.S. Patent 5,356,430.

[8] *Nadol*, col. 1. line 49-52.

both to the non-obviousness of the claimed invention and to the continuing usefulness of the scientific method.

Like so many assumptions that at one time seemed reasonable, this one has been experimentally disproven. In a declaration filed in response to the first office action, Dr. Nadol refers to actual tests involving the balloon described in the *Nadol* patent. The record does not indicate that the Examiner ever considered this declaration.[9] Had he done so, he would have learned that in clinical trials, the *Nadol* balloon simply did not function consistently with the foregoing assumption.

All the cited passage manages to achieve is to disclose that there are balloons in existence whose impedance was selected to match the impedance of the tympanum and the round window. This is neither the same as nor suggestive of what is recited in the independent claims. In fact, the clinical trials referred to in the declaration provide experimental proof that a balloon whose impedance matches the tympanum and round window does not necessarily have

> "an equivalent volume selected to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound"

as recited in claim 1. Indeed, were this the case, the clinical trials would have shown more promising results.

In the final office action, the Examiner also states that *Nadol* teaches a balloon in which

> "the materials for the membrane are selected for good acoustic transmission."

As a threshold matter, it is unclear why such a teaching would be relevant to the claims in the first place. Claim 1 does not recite a balloon made of "a material selected for good acoustic transmission." Claim 1 recites a balloon having a particular *equivalent volume*. Although the flexibility of the balloon's wall plays some role in determining equivalent volume, it is by no means the only factor. For example, it is quite possible to select a material for good acoustic transmission but to nevertheless degrade the balloon's equivalent volume in other ways, for

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[9] MPEP 716.01 "All declarations...traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action."

example, by placing seams that interfere with acoustic transmission, or filling the balloon with a gas with poor acoustic characteristics.

Nadol expressly teaches four criteria for constructing a balloon:

> "[F]our primary criteria are believed to be desirable. The balloon must be able to flex with both pressure changes and sound vibrations, must be of low permeability to gases, must be stable and non-toxic to the biological environment of the middle ear, and must be easily formed into the desired balloon shape."[10]

Had *Nadol* recognized the significance of equivalent volume, one might expect to have seen it mentioned in the foregoing passage. However, there is no discussion, or even mention of equivalent volume, either in the foregoing passage or anywhere else in *Nadol*. While it is true that flexibility is one contributor to equivalent volume, it is apparent from the following passage that *Nadol* lacks any disclosure of either a connection between flexibility and equivalent volume or any meaningful way to determine an appropriate flexibility:

> "The amount of flexibility which is necessary for good compressive response of a membrane and the balloon interior is unknown, and is difficult to quantify. When compared to air, the presence of any material in the middle ear will almost certainly reduce the level of sound perception by the inner ear. However, in comparison to the fluid found in a congested middle ear, a flexible compressible object with a thin balloon membrane should improve hearing. Therefore, the optimal amount of stiffness allowed in the balloon membrane must ultimately be determined by clinical observation."[11]

A proper rejection under 35 USC 102 requires that the reference disclose every element of the claimed invention.[12] The Examiner has not identified any such disclosure. Instead, the Examiner states that *Nadol*'s "basic tenet" involves providing pliant balloons for acoustic transmission.

Applicant is not seeking to patent a "tenet," either basic or otherwise. Applicant seeks to patent a *structure*, the limitations of which are recited in the claims. A proper rejection under

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[10] *Nadol*, col. 3, lines 5-10.

[11] *Nadol*, col. 4, lines 11-21.

[12] *Hybritech v. Monoclonal Antibodies*, 802 F.2d 775 (CAFC 1985) ("It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention"); *Akzo v. U.S. Int'l Trade Commission* 802 F.2d 1471 ("Under 35 USC 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference"); *Titanium Metals v. Banner*, 778 F.2d 775 (CAFC 1985) ("Anticipation under section 102 can be found only if a reference shows exactly what is claimed").

section 102 requires that each and every limitation of the claimed structure be taught by the reference.

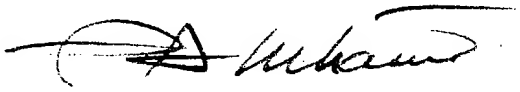
Almost by definition, any prior art reference would have the same "basic tenet" as an application under examination. Applicant is unaware of any requirement that patentability be predicated on a difference in "tenet" between the claimed invention and the prior art. Indeed, were the patent law consistent with the Examiner's position, *Nadol* would foreclose the patenting of any further improvement whatsoever in middle-ear balloon implants.

Despite having repeatedly cited *Nadol*, the Examiner has never identified specific passages in *Nadol* that teach the claim limitations. Instead, all the Examiner has done is to observe that both Applicant and *Nadol* teach implanting balloons in the middle ear. This is insufficient as a matter of law to maintain a rejection under section 102(b). Accordingly, Applicant requests that the rejection of claims 1 and 22 under section 102(b) be reversed.

Applicant encloses a $320 check in payment for the fee associated with filing of an appeal brief. No additional fees are believed to be due in connection with the filing of this appeal brief. However to the extent that additional fees are due, or if a refund is forthcoming, please adjust our deposit account 06-1050.

Respectfully submitted,

Date: 3/18/04



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